

REMARKS

Claims 1, 3, 4, 6, 11, and 14-26 are pending. No new matter has been added by way of the present amendment. For instance, claim 1 has been amended to recite that the tablet form is not coated with a film forming agent. Support for this amendment may be found at page 5, line 29 to page 6, line 4 where an optional coating of a film forming agent is disclosed. Claim 1 now recites the option where the film is not present. Claims 15 and 16 have been amended to remove the optional coating step. New claims 20-22 are supported by claims 1, 3 and 11, with the exception that the transitional claim language "consisting essentially of" is used. New claims 23-25 are supported by pending claims 1, 3 and 11, with the exception that the transitional language "consisting of" is used. Lastly, new claim 26 is supported by page 5, line 29 to page 6, line 4 where an optional coating of specific preparations is disclosed. The optional coatings of shellac, cellulose acetate phthalate, hydroxypropyl methylcellulose phthalate, polyvinyl acetate phthalate, cellulose acetate trimellitate and acryl and methacryl acid derivatives are known in the art as "enteric coatings." For instance, the Examiner's attention is drawn to U.S. Patent No. 5,525,354 to Posti et al. (of record), which discloses at column 1, lines 40-57 that these specific coatings are enteric coatings. In particular, Posti et al. discloses that these are enteric coatings which dissolve at a pH of from 5 to 7.2. Similar enteric coating materials are disclosed at page 26, lines 9-20 of

WO 96/21429 to Sherwood (of record). It is thus these types of enteric coatings, which are disclosed by the present specification as optional, which are excluded from claim 26. Accordingly, no new matter has been added.

In view of the following remarks, Applicants respectfully request that the Examiner withdraw all rejections and allow the currently pending claims.

Issues under 35 U.S.C. § 103(a)

Claims 1, 3, 4, 6, 11 and 14-19 stand rejected under 35 U.S.C. § 103(a) as being obvious over Posti et al., U.S. Patent No. 5,525,354 (hereinafter referred to as Posti '354) in view of WO 96/21429 to Sherwood (hereinafter referred to as WO '429) and Remington's Pharmaceutical Sciences. Applicants respectfully traverse this rejection.

The Examiner alleges that one of ordinary skill in the art would have been motivated to substitute "silicified" microcrystalline cellulose for microcrystalline cellulose and silicon dioxide. Applicants continue to traverse this rejection and incorporate all arguments of record.

The Examiner's attention is directed to Posti '354 at column 1, lines 40-57 where it is disclosed that the preparation of the drug delivery form is "enteric coated with a film which dissolves at a pH of from 5 to 7.2." However, the present claims do not allow for such a coating. Therefore, a deficiency exists in the disclosure of Posti '354 in that there is not motivation to

remove the enteric coating of Posti '354 from the tablet forms. In fact, at column 1, line 40 of Posti '354, it is disclosed that an objective of the invention is achieved only if the enteric coating is present.

Neither WO '429 nor Remington's Pharmaceutical Sciences cure this deficiency. For instance, WO '429 discloses at page 26, lines 9-20 that particular types of enteric coating materials, which are the same as the materials discussed by Posti '354, may be employed. Also, Remington's Pharmaceutical Sciences does not provide any relevant disclosure on this issue.

Accordingly, no motivation exists to remove the enteric coating of Posti '354 or WO '429. Therefore, the present claims are distinct from the cited art. Whether taken alone or in combination, the cited art fails to suggest or disclose the presently claimed subject matter. Accordingly, no prima facie case of obviousness exists. Reconsideration and withdrawal of the outstanding rejection are therefore requested.

If the Examiner has any questions or comments, please contact Craig A. McRobbie, Registration No. 42,874 at the offices of Birch, Stewart, Kolasch & Birch, LLP.


If necessary, the Commissioner is hereby authorized in this, concurrent, and further replies, to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fee

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required under 37 C.F.R. §§ 1.16 or 1.17; particularly, extension of time fees.

Respectfully submitted,

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